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Sustainable Polymers targeted at the Surgical and Otolaryngological Applications: Circularity and Future

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Abstract

The ongoing climate changes, high air and noise pollution have significant impact on humans' health. This influence is especially visible in otolaryngology, which focuses on respiratory and hearing systems disfunctions. However, even though surgeries are done in response to diseases related to climate changes, they also have a negative impact on the environment, mostly connected with the inherence of single-use fossil fuel derived polymers. This leads to a self-perpetuating emission of greenhouse gases, as human beings developed a lot of synthetic materials to combat climate change derived dysfunctions, which itself endangers human health in a chaotic circular chain. Mitigating issues arising from using synthetic plastics would be possible by imparting biodegradable polymers from renewable resources. Nowadays, sustainable polymers are adopted mostly in emerging fields of medicine, such as 3D printing, tissue engineering of drug delivery systems. Sustainable polymers are particularly useful in otolaryngology, e.g., in the form of nasal drug eluting stents or bone substitutions. Nevertheless, some limitations in wider usage of renewable polymers in surgery should also be underlined, mainly related to lack of legislation, clinical considerations, and also inadequate materials' circularity. Herein we briefly overviewed commonly used polymers in general surgery and otolaryngology, defined the trends in sustainable polymer usage in these fields, and highlighted the limitations in renewable polymers applications together with possible solutions. What this short review emphasizes, is that the significant increase in interest and demand for sustainable solutions will revolutionize the future of clinical treatments, where contribution to climate change and waste management will be centered in decision making protocols.

Keywords: renewable polymers, otolaryngology, surgery, implants, bioresorbable, biodegradable

1. Introduction

The ongoing climate changes, high air and noise pollution have significant impact on humans' health. The total estimated greenhouse gases (GHG) emission from plastics lifecycle was estimated to be around 1.8 billion tonnes of CO_2 equivalent [1]. Although it is projected that the GHG emissions will continue to grow, there are many initiatives to reduce the impact of polymer sector on environment. An example of such actions could be finding the correlations between procedures used in selection of biomaterials with climate change and sustainability concerns, to help in choosing greener solutions [2]. Recently, the biopolymers usage in various applications ranging from packaging to medical devices significantly increased. In medicine, they are used mostly in drug delivery, sutures or adhesives thanks to biocompatibility and biodegradability. The additional advantage of biopolymers over fossil fuel derived polymers are the lower emissions of CO_2 and reliance on renewable resources [3].

The current climate changes are drastically affecting human health and well-being [4]. Respiratory and hearing systems, being very fragile, are one of the most affected parts in our body. It was concluded that due to climate changes and worsening air pollutions there is an increase of number of patients with exacerbate allergic rhinitis, asthma and other respiratory problems such as severe chronic rhinosinusitis [5,6]. Together with the number of patients, the hospitalization costs will grow [7]. Additionally, the problems associated with the ear, nose and throat (ENT) disease burden is largely underrecognized in social determinants of health [8]. Many of the ENT related disorders can be treated with proper medications. However, overlooking the symptoms can lead to serious problems, requiring even surgical interventions. This is especially true in developing countries, where there is limited access to healthcare [9]. While there are many acquired diseases, there are also many congenital conditions that require surgical intervention. Such disorders are manifested mainly in the form of bone and cartilage deformations, overgrowths or perforations.

The most common otolaryngological surgeries could be divided into five anatomical groups: otological, endonasal, facial, transoral and combined head and neck surgeries [10]. During each intervention, a series of different polymer-based dressings, sutures, implants or instruments are being used. Most of them are single-use only or cannot be later reused in current recycling systems, often due to legal and safety reasons. To fit in the medical waste regulation, increase in usage of polymers from renewable resources seems to be rational way to reduce the carbon footprint and climate changes, affecting the human health. Thus, this paper focuses on defining the current usage of polymers in otolaryngology applications, placing particular emphasis on defining the sustainable polymers and the possible angles for increase in renewable resources utilization for surgical equipment in this field. Due to changes in the perception of patients' own contribution to climate change and extended producer responsibility for handling polymer waste, a significant increase in interest and demand for sustainable and circular solutions in medicine is predicted. The advancement of renewable polymers in surgery will increase the circularity of medial sector, thus lowering its impact on global warming, and, in consequence, interrupt human health endangering, chaotic circular chain of synthetic products usage for fixing climate changes derived disorders.

2. Polymers in general surgical appliances

Polymeric materials possess many properties desirable in the medical industry. The usage in medicine is responsible for less than 1% of the global plastics market in volume, but more than 4% in value [11]. The most important advantages of polymers, in comparison to other material types, are: design versatility, toughness, low weight, cost and simple sterilization of products. Polymers have a significant share in the general surgical equipment, which are described mostly as the I and II class of FDA devices, e.g., simple surgical devices, catheters, gloves, bandages or diagnostic equipment. The examples of polymer used in general surgical appliances are presented in Table 1. The mostly used polymers are polyolefins, e.g., polypropylene (PP), polyethylene (PE), polystyrene (PS), polyesters like poly(ethylene terephthalate) (PET) or poly(lactic acid) (PLA) and elastomers, including poly(vinyl chloride) (PVC), thermoplastic polyurethane (TPU) and silicones (mostly polydimethylsiloxane – PDMS). The medicinal waste handling is an emerging problem with growing generation trend worldwide, which was further accelerated during COVID-19 pandemic [12–14]. As for surgical waste, it is considered that 20 to 30% of total medicinal waste in USA is produced during surgeries, which totals for more than 1.8 million tons of waste [15,16]. Although most of the used polymers are generally recyclable, medical waste is usually considered contaminated and cannot be directed to the common municipal waste streams. To improve safety of waste handling, medical waste is often treated with steam (e.g., autoclave) to disinfect of sterilize scraps. After that, medical waste is usually incinerated [17] or landfilled [18], but rarely recycled [19]. However, researchers suggest that only 15% of the total medical waste is hazardous [20], thus it is essential to distinguish such contaminated waste from general medical waste stream to improve the recyclability.

Although it seems beneficial to use polymers form renewable sources to lower the carbon footprint in medicine, most of the polymers used in surgeries are not sustainable. They are mostly used in regard to their biodegradability or bioresorbability in human body as disappearing sutures, screws and fixation plates. Among them, only PLA gained more attention recently mostly related to its widespread in 3D printing industry, as it was commonly used for ad hoc production of required equipment during COVID-19 pandemic. Personal protective equipment (PPE), parts of respiration devices, mask fitters, face masks, door openers or oral and nasopharyngeal swabs were frequently printed and used [21,22]. The usage of PLA is rather limited to single-use applications, due to low thermal and chemical resistance, which significantly narrows the possible sterilization techniques [23,24]. The examples of fossil-based and renewable polymers and their applications in general medicine and otolaryngology were shown in Figure 1. Apart from fully sustainable polymers, there are attempts for using naturally-derived substrates as an alternative to fossil fuels to lower greenhouse gas emissions. Such polymers, marked as "partially renewable" in the Table 1, have identical properties to their petrochemical derivatives. For example, bio-PE is produced from ethylene coming from dehydration process of sugarcane or lignocellulose derived ethanol [25,26], bio-PP is produced by polymerizing propylene obtained using steam cracking of enriched vegetable oils [27] and in bio-PET production, the ethylene glycol derived from ethanol is being used [28]. However, such materials are not yet widely present on the medical market, mostly due to long certification process by regulatory bodies. Examples of such emerging bio-based polymers are Rilsan polyamide (PA) 11 from Arkema [29] used for catheters, medical tubing or IV bags, ECOFUSE undisclosed polymer type nonwoven textile from Roswell Textiles used for production of Precision Eco™ facemasks [30] and Mediprene thermoplastic elastomers (TPE) from HEXPOL in form of LoFric® Elle™ single use urinary catheter from Wellspect [31,32].

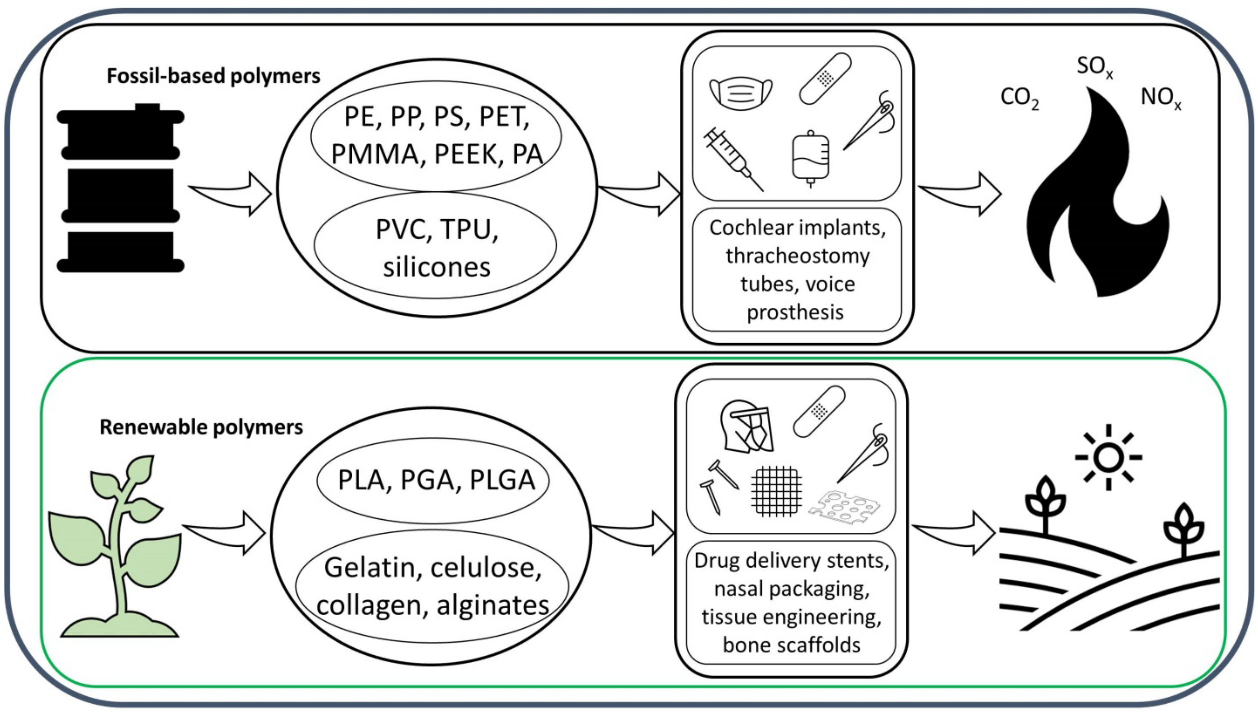

Figure 1. *Fossil-based and renewable polymers: differences in medical applications.* Polymers are widely used in both general surgery and otolaryngology. However, as presented, many of the fossil-based polymer devices are intended for single-use only: e.g., syringes, packaging, patches, blisters, PPEs. Considering that handling of medical waste mostly focuses on incarnation and landfill, it is reasonable to use polymers form renewable sources to lower the carbon footprint in the medicine sector. Sadly, most of the polymers used in surgeries are not sustainable. Naturally-derived polymers are mostly used in regard to their biodegradability or bioresorbability in the human body as sutures, fixation plates or screws.

Table 1. *Examples of polymers used in general surgical appliances.* The most used polymers are polyolefins (PE, PP, PS), polyesters (PET, PLA) and elastomers (PVC, TPU, silicones). Among fully renewable polymers, only PLA has the applications replacing the fossil fuel derived polymers. Some of partially renewable materials are used in medicine (bio-PE, bio-PP, bio-PET), but their total impact on GHG is still discussed.

Polymer	Applications	Highlights	Recyclable	Renewable
PE	Containers, films, pouches, patches, PPE	Reusable, inert, low cost, impact resistance	Yes	Partially
PP	Films, syringes, sutures, drapes and gowns, containers, trays, PPE	Reusable, heat and stress resistant, low cost, water proof	Yes	Partially
PS	Petri dishes, flasks, pipettes, diagnostic instruments, trays	Transparency, low cost, sterility, adherence to cells	Yes	No
PET	Trays, cables, tubing, meshes, urinary and bloodstream catheters, PPE	Transparency, stress resistant, flexible, barrier properties	Yes	Partially
PBT	Syringe pump, scalpel, blade holders, caps, lancing devices	Impact resistance, high tensile strength, electrical insulator	Partially	No
PLA	Sutures, ligature clips, staples, retractors, fixation plates, PPE	Biodegradability, biocompatibility, 3D printability, high tensile strength	Partially	Yes
PGA	Sutures, fixation plates and screws, non-woven felts	Biodegradability, biocompatibility, barrier properties, high tensile strength	Partially	Yes
PLGA	Sutures, nonwoven fabrics, fixation screws	Tunable biodegradability, biocompatibility	Partially	Yes
PC	Reservoirs, high-pressure syringes, housings filters handles	Transparency, impact resistance, dimensional stability	Partially	Partially
PVC	Luer connectors, blisters, fluid containers, oxygen facemasks	Transparency, elasticity, chemical resistance, low cost	Yes	No
PMMA	Drainage, fluid containers, breathing apparatus, Y-sites, adhesives	Hemostatic, bonding properties, hydrogels preparation	Partially	No
PEEK	Syringes, keyhole surgery devices, catheters, retractors	Fatigue, heat and chemical resistance, tensile strength, stiffness, inert,	No	No
PSU	Membranes and fluid handling, handles, knobs, trials and grips	Heat, impact and chemical resistance, inert	No	No
TPU	Catheters, valves, needleless syringes, shunts, bags and tubing	Highly tunable properties, elasticity, wear resistance, tear strength	Partially	Partially
PA	Sutures, staples, meshes, catheters, membranes	High tensile strength, chemical resistance,	Partially	Partially

Silicones	Catheters, endoscopes, handles, tubing, needles coating	Temperature resistance, transparency, low surface roughness, long-term stability	No	Partially
Poly-p-xylene	Needles, catheter, electrodes, stents, epidural probes, cannulas	Conformal coating, barrier properties, low surface roughness, electrical insulator	No	No

PE – polyethylene, PP – polypropylene, PS- Polystyrene, PET- poly(ethylene terephthalate), PBT – poly(butylene terephthalate), PLA – poly(lactic acid), PGA – poly(glycolic acid), PLGA - poly(lactic-co-glycolic acid), PC – polycarbonate, PVC – poly(vinyl chloride), PMMA – poly(methyl methacrylate), PEEK – polyetheretherketone, PSU – polysulfone, TPU - thermoplastic polyurethane, PA - polyamide

3. Polymers in otolaryngological applications

The previously mentioned five categories of otolaryngological surgeries can be further summarized into three main categories: otological, rhinological and pharyngolaryngeal. The first field focuses mainly on ears and hearing-related problems. The second one targets nose, nasal sinuses, skull base and breathing related diseases. The last category concentrates on pharynx, larynx and variety of conditions, including breathing, voice or gastric disorders. For each of these fields, specific solutions were developed over the years. In this regard polymers are gaining more and more attention each year, in many cases offering superior properties to traditional metal solutions, e.g. in the field of bone reconstruction [33]. The brief summary of polymer applications in otolaryngological surgeries is presented in Table 2. There are two polymer types applicable in most of the reviewed fields, mainly silicones and PTFE. The silicones are used due to their excellent flexibility, softness, low surface friction, resistance to human body fluids and overall biocompatibility [34]. On the other hand, PTFE is used thanks to its inertness, biocompatibility, low surface friction, long service time and ability to easily coat other materials [35]. However, both of these materials lack antibacterial, antistenosis, or tissue integration properties, which limit its application to structural and removable implants. To overcome these downsides, TPU is used instead of silicone in some cases. Polymers are also often used in composites creation (Cortoss® - bisglycidal dimethacrylate with calcium phosphate micro-glass cement) to combine the properties of different material types [36]. Similarly to the trend observed in general surgical applications, in the ENT appliances sustainable polymers are used mostly in regard to their biodegradability or bioresorbability in human body as disappearing and cell growth promoting devices. However, their presence in this field is much more pronounced due to higher need for drug delivery into closed cavities, tissue regeneration and support. Thus, rhinology is the main field of sustainable polymers usage in otolaryngology. Here, some of state of the art solutions are being developed and introduced as commercial products. One of the most important devices are drug delivering nasal sinus stents, which not only reinforces and supports sinuses after endoscopic sinus surgery, but also delivers drugs significantly lowering the recovery time and increase patients' well-being [37]. Other emerging naturally-derived appliances are based on alginates (Algoderm®) [38], gelatin (Cutanplast®) [39] or carboxymethylcellulose (CMC) (Prolaryn®) [40] and used for variety of applications, including wound healing or vocal fold medialization. Other interesting field of sustainable polymers usage is tissue engineering, but despite numerous literature examples reporting successes in ENT field, the full potential of 3D bioprinting method essential to personalize the engineered tissues has yet to be realized [41]. The new solutions for otolaryngology based on sustainable polymers are developed and approved each year, e.g., Novapak® (chitosan and cellulose) or Latera® (poly-L-lactide), which FDA approved in 2020 and 2019, respectively [42,43]. The search for new polymers for usage in otolaryngology is still commencing, focusing on testing [44] and blending [45] various commercial materials or developing new ones [46]. In the field of bioprinting and tissue engineering naturally-derived hydrogels from collagen, agar or algae could be used [47,48].

Examples of newly developed devices based on sustainable materials for otolaryngology are presented in Fig. 2.

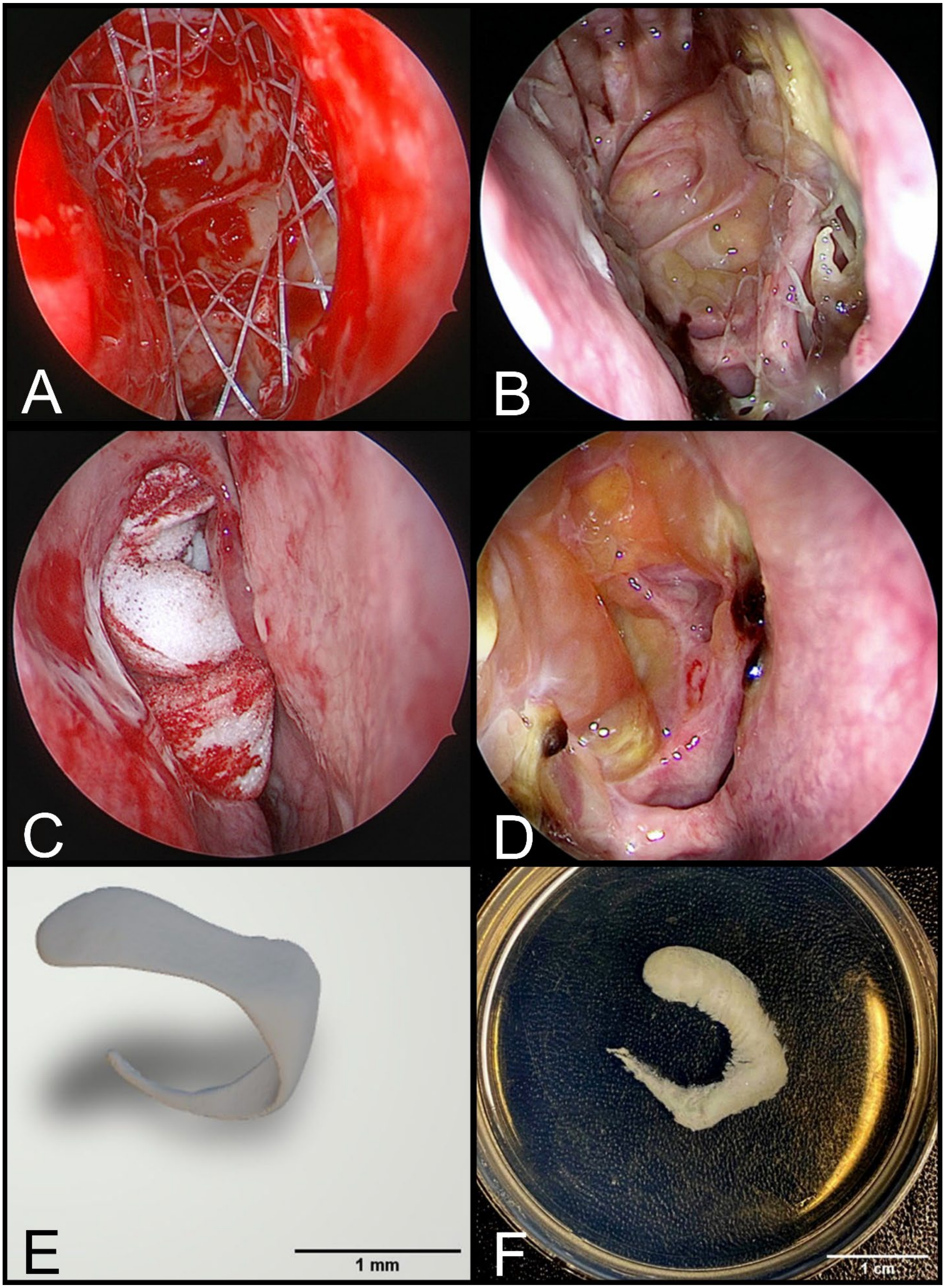
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Figure 2. *Examples of newly developed devices based on sustainable materials for otolaryngology.* BIOSORB® Steroid-eluting sinus stent made from poly(lactic-co-glycolic acid) (PLGA) placed in the left side postoperative ethmoid sinus cavity after endoscopic sinus surgery (ESS) – at day 0 (A) and at day 30 (B). In comparison, Nasopore® dressing made from polyurethane (PU) placed on the right side left postoperative ethmoid sinus cavity after ESS – at day 0 (C) and at day 30 (D). BIOSORB® application resulted in significant regeneration of sinus connected with much lower need for postoperative interventions and lower polyp formation in comparison to fossil fuel derived Nasopore® [49]. The right lower lateral nasal cartilage model based on CT imaging as 3D model (E) and 3D bioprinted implant utilizing neutralized type I collagen from patient-derived nasal septal cartilage as bioink after 30 min incubation in 37°C and removal of gelatin support (F). The bioprinted cartilage implant offered similar in vivo and in vitro properties in comparison to commercially available Chondro-Gide® type I/III collagen membrane scaffolds. The study showed the feasibility of producing cartilage implants from patients' own cells [50].

Table 2. *Examples of polymers used in otolaryngological applications.* Two polymer types are applicable in most of reviewed fields, mainly silicones and PTFE. Similarly to general surgery, renewable polymers in otolaryngology are used mostly in regard to their biodegradability or bioresorbability in human body as dressings, drug delivery systems or hydrogel coating. However, their presence in this field is much more pronounced due to higher need for drug delivery into closed cavities, tissue regeneration and support.

Field	Application	Polymer	Description	Ref
Otology	Cochlear implants	Silicone, PTFE	Complex, multimaterial device, which consists of two parts: external, which receives, processes and transduces the sound and internal, which receives processed sound and directly stimulates the cochlear nerve. Polymers are used mostly for coating of the devices. Examples: HiRes™, SYNCHRONY 2.	[51]
	Tympanostomy tube	Silicone, PTFE	Tube is implanted into middle ear to aerate the inner parts of ear and prevent fluid accumulation. Recently, single-use devices for automated tube placement were introduced with integrated blades and local anesthetic drug delivery. The surgery is performed by activation of the control button on the device, which simultaneously retracts the knife and deploys the preloaded tube. Examples: Hummingbird®, Tula®.	[52]
	Middle-Ear prosthesis	HDPE, PTFE, PMMA, Silicone	Middle-Ear prosthesis is used for reconstruction of the bone structure damaged after otitis media or Meniere's disease. As the middle ear structure is very delicate, surgery has to be always personalized, because there is no one-fits-all strategy. There is no predefined solution, but polymer materials are often used for modeling required elements. Examples: Plastipore, Polycel.	[53]
Rhinology	Sinus reinforcement	PDLLA, PLGA, PEG, PCL	Nasal sinuses require the reinforcement and anti-inflammatory treatment after endoscopic sinus surgery. Such devices significantly lower the recovery time and increase patients' well-being. For this purpose, biodegradable stents packed with corticosteroids can be used. Examples: PROPEL®, BIOSORB®.	[54]
	Nasal packaging	PVAc, PVA TPU, alginates, CMC	Nasal packaging is often used during and after surgeries to control bleeding. It is also used to prevent restenosis, synechiae formation or middle turbinate lateralization. Such devices are available as restorable or removable. Examples: Nasopore®, Algoderm®.	[55]
	Septum Cartilage	Silicone, PTFE,	Nasal splints are often used in operations of nasal septum. They provide	[56]

	splints	gelatin, polydioxanone	tissue support, accelerate mucosal healing and prevent deviations or perforations of septum during the healing period. Examples: Silastic, Doyle Combo Splint.	
Pharyngolaryngeal	Tracheostomy tube	PVC, TPU, silicone	Tracheostomy tube is implanted to the space between trachea and skin to bypass upper airway obstructions, help with management of secretions or provide ventilation during respiratory failure. Examples: Shiley®, Tracoe®.	[57]
	Voice prosthesis	Silicone, PTFE, TPU	Voice prosthesis is placed through a puncture in the wall separating trachea from the esophagus. The prosthesis has stoma, which can be covered to make sounds by pushing air from lungs through the valve and further into the mouth. Examples: Provox®, Phonax®.	[58]
	Vocal cord	Pernament - PDMS, PTFE; Temporary - CMC, gelatin, collagen	Paralyzed vocal cord can be healed permanently using an implant or temporarily by injection of the thyroarytenoid muscle into the paralyzed cord. Examples: Prolaryn®, Radiesse®.	[59]
Common	Bone reinforcement and osteosynthesis	PGA, PLLA, PDLLA,	Biodegradable polymeric bone reinforcements are a viable alternative to titanium implants, mostly used in that field. Polymers are used in the form of plates and screws. Examples: Biofix, Polymax.	[60]
	Bone substitution	HDPE, PEEK, PMMA, PLA, PCL, PLGA, collagen, alginates,	For substitution of bone both resorbable and non-resorbable are used. Usually, polymers are used in the form of scaffolds or membranes, often as composites with other materials. Examples: Bio-Gide®, Cortoss®.	[33]
	Other tissues engineering	Collagen, PCL, alginates, GelMA, cellulose	The application of polymers in ENT tissue engineering is mostly focused on bioprinting and usage of hydrogels. Most successful attempts were done in trachea and nasal cartilage reconstruction. Polymers are often accompanied by other materials and cells. Example: DeNovo® NT.	[41]

PTFE – poly(tetrafluoroethylene), HDPE – high density polyethylene, PMMA - poly(methyl methacrylate), PDLLA – poly(D,L-lactic acid), PLGA - poly(lactic-co-glycolic acid), PEG – poly(ethylene glycol)/poly(ethylene oxide), PCL – polycaprolactone, PVAc – poly(vinyl acetate), PVA – poly(vinyl alcohol), TPU - thermoplastic polyurethane, CMC – carboxymethylcellulose, PVC – poly(vinyl chloride), PDMS – poly(dimethylsiloxane), PGA – poly(glycolic acid), PLLA – poly(L-lactic acid), PEEK - polyetheretherketone, PLA – poly(lactic acid), GelMA – gelatin methacryloyl

4. Conclusions and future prospects

Polymers are widely used in both general surgery and otolaryngology and have displaced metals and ceramics in many applications. However, as presented, many of the polymer-based devices are intended for single-use only: e.g., syringes, packaging, patches, blisters, PPEs. Considering that handling of medical waste mostly focuses on incarnation or landfill, it is reasonable to use polymers form renewable sources to lower the carbon footprint in the medicine sector. Sadly, most of the polymers used in surgeries are not sustainable. Naturally-derived polymers are mostly used in regard to their biodegradability or bioresorbability in the human body as sutures, fixation plates or screws. Basically, the only exception from this trend is PLA, which gained more attention, as it was commonly used for ad hoc production of required equipment during COVID-19 pandemic. However, there are some initiatives to at least partially replace fossil fuels in polymer synthesis in form of bio-PE, PP or PET. Nevertheless, the present LCA analyses of whole production process and waste handling of such polymers do not show significant advantages over the fossil fuel derived ones [61]. In otolaryngology, the usage of sustainable polymers is much more pronounced, as there is much higher need for drug delivery into closed cavities, tissue regeneration and support than in conventional surgeries. The naturally-derived polymers are mostly represented in rhinology applications as drug delivering stents, nasal packaging or cartilage splints.

There are three possible reasons limiting wider usage of sustainable polymers:

- Currently used fossil fuel-based polymers are sufficient for most of the applications and there is no driving force to change them. Medical personnel are used to handle syringes from PP, hoses from silicone or scalpel handles from PS and do not seek alternative solutions.
- The certification process for application of new materials is long, costly and laborious, thus for many companies it is not worth to introduce new, bio-based materials which would have to compete with price with currently used materials. It can be seen that many sustainable polymers are being used in new fields, where traditional polymers were not used, or their application was limited, thus there was no price competition.
- The availability of naturally-derived polymers is much lower in comparison to traditional polymers, hence there are risks of unavailability of production resources and supply interruption. To successfully implement new polymer products on the market, manufacturers have to be sure that the amounts of material available on the market is sufficient for maintaining production, even if other stakeholders will start to use it.

However, despite these limitations, authors predict that usage of sustainable polymers will increase in the near future. The lack of change driving force will be probably changed due to rising climate changes awareness, so the usage of environment friendly devices will be one of the main advertisement points of medical industry, especially in private medical care sector. On the other hand, the legislation could probably force some level of renewable polymers usage in the medical industry, similarly to newly implemented directive about single-use products in the European Union. The second limitation could be omitted by scale effect and the laws of supply and demand. Customers are willing to pay more for environmentally friendly solutions, thus the manufactory price of newly developed devices can be higher to compensate for the expenses for certification process. Furthermore, the increase of production scale will give further savings. As for the last limitation, the supply of naturally-derived polymers is growing every year and nowadays can be sufficient for big scale production.

Moreover, there are few sustainable polymers not yet explored in the medical industry, which have properties similar to commonly used ones. Polyhydroxyalkanoates (PHA), being the energy storage material for bacteria, belong to polyesters family. There are few polymers in this family worth mentioning, e.g., poly(3-hydroxybutyrate-co-3-hydroxyvalerate) with properties similar to rigid PS and variations with higher number of sidechains have similar behavior to low density PE [62]. Additionally, PHA polymer family is characterized by high barrier properties for O_2, CO_2 and odors, in some cases even higher than polyolefins [63]. There are many new factories starting to produce this type of polymers, so the supply and availability is constantly growing [64]. Another promising polymer type is poly(butylene succinate) (PBS). It is marketed as a biodegradable alternative to polyolefins [65]. PBS was first synthesized using fossil fuels, but recently the substrates are changing to sustainable ones coming from glucose [66]. The research on this polymer in medicine mainly focuses on wound dressings and drug delivery [67]. Thermoplasticc starch [68], chitosan [69,70], lingocellulose [63] or naturally derived hydrogels [71,72] are other sustainable materials for usage in medicine.

Overall, we can expect the significant increase in interest and demand for sustainable polymers usage in both general surgery and otolaryngology in near future, due to changes in the perception of patients' own contribution to climate change and extended producer responsibility for handling polymer waste.

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The Author(s) declare(s) that there is no conflict of interest

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